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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

The amendment filed 02/23/2009 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search.

Applicants have added a new limitation to the end of the claim 89 and others. The material taken out of the preamble had no effect, as it was part of the preamble, for reasons set forth previously, although of course it was unclear.

However, the new language "and wherein said medicament shows an effect only at the applied location" would trigger a new rejection under 35 USC 112, paragraph 2.

First, what does it limit? Does it limit the compound, i.e. does it exclude those compounds which fail to meet this claim limitation? Or does it limit the method of treating, i.e. one does the treating in such a way that the claim limitation can be met. And if the latter is true, how is that done? This is a result, but there is no step to say how this is done.

Second, it is by no means clear how one can determine that the limitation has been met, because it involves proving a negative. If there were so much as one single effect outside the location, then the claim limitation is not met. How could one show that this didn't occur?

Third, it would not be clear what is meant by "applied location". If it is applied topically to the skin or the lining of the lung, does the "applied location" cover only the skin and lung lining, or would the tissue right below the skin or lung lining be considered part of

the same location? In addition, if the answer to that is "no", a drug on the skin is applied to the epidermis. Is it just the epidermis" which is considered the applied location, or is the dermis, and the hypodermis also considered part of the same location. In other words, if the drug applied to the epidermis showed an effect in the hypodermis, is that the applied location or beyond the applied location?

Proposed claim 121 is a brand new utility and would raise not only enablement issue but an indefinite issue as well (which interferon?)

The amendment also cannot be entered because it presents additional claims without canceling a corresponding number of finally rejected claims. See Box 3(d) of PTOL-303 and MPEP 714.13(III) which states, "(D) Since the amendment presents additional claims without canceling any finally rejected claims it is not considered as placing the application in better condition for appeal. Ex parte Wirt, 1905 C.D. 247, 117 O.G. 599 (Comm'r Pat. 1905)."

There may be other issues as well.

Applicants' remarks are not useful in places, and not understood in other places. The remarks state, "Applicants first point out that claims 89 and 90 have been amended. Applicants submit that those amendments remove the present claims from the scope of the prior art." No specific explanation for this is provided. The claim now says allergies, but the examiner has pointed out that claim 13 in the reference has allergic diseases.

In other places, the examiner is at a loss to understand applicants' reasoning. For example, from the first page of the rebuttal arguments (page 21): "The Examiner states that it is "simply untrue" that transdermal administration is not equivalent to topical administration." That is <u>not</u> what the examiner stated. From page 4:

response (e.g. line 2 of claim 89)." Agreed, and true of claim 114 as well. Applicants continue:

"Nowhere in the reference is there any teaching or suggestion of topical administration of any compound as in the present claims. Such route of administration disclosure as is presented by '381 is at col. 20, lines 34-42, and only oral or parenteral administration, i.e. systemic routes of administration are disclosed."

This is simply untrue. Applicants have ignored the portions of the reference which

What the examiner was saying was untrue was applicants' description of the reference. The examiner was not saying anything about what is equivalent to what.

The remarks continue: "The Examiner concludes that "[a] transdermal medicine is by its very nature topically applied. Dermis means skin. Transdermal formulations . . . are applied to the skin." (Office Action, page 4). Applicants submit that a topical administration is NOT a systemic administration."

This is a total non-sequitur. The portion of the examiner's statement which was quoted had nothing at all to do with the relationship between topical administration and systemic administration. Furthermore, it's irrelevant. The term "systemic administration", or its equivalent did not appear in the rejected claims, and the claim was silent as to whether the administration was systemic or was not systemic.

Next, applicants stated, "Moreover, the Examiner should only take official notice of a fact, unsupported by documentary evidence only when it is "common knowledge in the art" which is "capable of instant and unquestionable demonstration as being well known." (MPEP 2144.03(A))."

What exactly is the point here? Yes the examiner states that "transdermal medicine is by its very nature topically applied" is "common knowledge in the art". The statement

"Dermis means skin" and the statement "Transdermal formulations . . . are applied to the skin" are likewise "common knowledge in the art".

To give another example, the next page has

"Sprays

The Examiner states that '381 mentions "propellants which are used only in sprays... [which] have two uses, into the lungs, and again, onto the skin." However, in the claim directed to "inhalation" the ring A is recited as being a heteroaromatic ring (claims 100-106), or in instances where ring A is benzene, the ring A is substituted by an alkyl amino substituted ester group (claims 107-114). The particular compounds of claim 120 are not mentioned in the '381 patent either. Thus, Applicants request that the Examiner withdraw the rejection regarding claims 113 and 120."

The examiner did indeed argue that the reference teaches sprays, and that sprays, whether administered to the skin or to the lung, is a form of topical administration. But what is this "the claim directed to "inhalation"..."? Claims 1001-6 are not method claims, and are not in fact rejected over the reference. As for "withdraw the rejection regarding claims 113 and 120", claim 120 is not rejected over the reference. As for claim 113, that is rejected, but the claim is dependent on claim 90, not claim 100. Claim 90, unlike claim 100, is not required to have A as a heteroaromatic ring, nor is it the case that "the ring A is substituted by an alkyl amino substituted ester group" in claim 113. That is, while applicants lump together claims 107-114 as where ring A is benzene, the ring A is substituted by an alkyl amino substituted ester group, this is simply not true for claim 113.

Applicants are simply confused about the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Mark L. Berch/
Primary Examiner
Art Unit 1624

3/3/2009